

REMARKS

Claims 8-14, 21, 25 and 26 have been canceled. Claims 16-20 and 22-24 are currently pending.

Independent Claim 20 was rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Green, et al. As set forth below, this rejection is respectfully traversed since Green, et al. fails to teach or reasonably suggest all of the limitations of Claim 20.

Claim 20 recites “[a] method for the inhibition and/or treatment of systemic infections in humans or vertebrates comprising *administering to humans or vertebrates having a systemic infection caused by pathogenic bacteria* a composition comprising an effective amount of a fermentable dietary fiber or a mixture of fermentable dietary fibers, wherein the composition is administered orally, through tube feeding or rectally” [emphasis added].

According to the Official Action, Green, et al. teaches a “nutritional” composition which “... may be used to clear toxic compounds from the intestines by providing stool bulk and substrate for intestinal flora” (paragraph spanning pages 3 and 4 of the Official Action). There is no teaching or suggestion in Green, et al., however, of a method for the inhibition and/or treatment of systemic infections as set forth in Claim 20 comprising *administering to humans or vertebrates having a systemic infection caused by pathogenic bacteria* a composition comprising an effective amount of a fermentable dietary fiber or a mixture of fermentable dietary fibers.

In arriving at the rejection of the claims, the Official Action recites:

The Office does not have the facilities for examining and comparing applicant’s product with the product of the prior art in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1302 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.)

and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). (page 4 of the Official Action).

The present invention, however, is directed to a method and not to a product. The case law cited by the Examiner is directed to rejections of product claims (i.e., product or product-by-process claims) wherein a prior art reference appears to teach a substantially identical product. See, for example, MPEP §2112 and §2113. For at least the reasons set forth below, it is respectfully submitted that the claimed method is patentably distinct from the method disclosed by Green, et al. As such, the requirement that the applicant prove that the “claimed products” are functionally different from those taught by the prior art is inappropriate in the context of the presently claimed invention.

The Official Action also recites:

. . . applicant’s claims read on ingesting a fiber material whereby the ingestion of that fiber material prevents or inhibits systemic infections of humans or vertebrates who are at an increased risk of systemic infections. What is it about applicant’s claimed fiber that is different from the prior art? (page 4 of the Official Action).

Contrary to the above assertion, it is respectfully submitted that the applicants claims do not “read on ingesting a fiber material whereby the ingestion of that fiber material prevents or inhibits systemic infections of humans or vertebrates who are at an increased risk of systemic infections”. Rather, Claim 20 is directed to a method of inhibiting and/or treating systemic infections in a particular sub-population of humans or vertebrates (i.e., a sub-population having systemic infections). The Official Action has pointed to no teaching in any prior art reference which would suggest to one of ordinary skill in the art the claimed method for the inhibition and/or treatment of systemic infections.

Moreover, whether or not any particular property of a composition is inherent is not dispositive of the patentability of the method of use of that composition. Thus, it is well

established that a new and unobvious use of even a known composition may be patentable as a process or method of using the composition. In re Hack, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). See MPEP §2112.02. This rationale also extends to methods of treatment using compounds having a known pharmacological activity. See, for example, In re Merck & Co., Inc., 231 USPQ 375 (Fed. Cir. 1986). In Merck, the CAFC analyzed claims directed to the method of use of the compound amitriptyline to treat depression. The prior art taught that amitriptyline was a psychotropic drug which reacted on the central nervous system. However, the drug was not known to be an antidepressant. The CAFC stated that, “in order to show obviousness, *it was necessary to determine from knowledge already available in the art at the time of appellant's invention that one skilled in the medicinal chemical art would have expected amitriptyline to be useful in the treatment of depression in humans*” [emphasis added]. Merck, supra, 231 USPQ at 378.

Therefore, based on the holding in Merck, in order to establish a *prima facie* case of obviousness for the subject matter of Claim 20 it would be necessary to establish that one of ordinary skill in the art would have expected a composition comprising a fermentable dietary fiber or a mixture of fermentable dietary fibers to be useful *in the inhibition and/or treatment of systemic infections* in humans or vertebrates. The Official Action has pointed to no teaching or suggestion in Green, et al. or in any other reference that would suggest a method as claimed for the inhibition and/or treatment of systemic infections in humans or vertebrates having a systemic infection caused by pathogenic bacteria.

In order to establish *prima facie* obviousness, all of the limitations of a claim must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). See MPEP §2143.03. Since the Official Action has failed to address each and every limitation of the claimed invention, it is respectfully submitted that the Official Action has failed to establish a

prima facie case of obviousness. It is therefore respectfully requested that the rejection of Claim 20 be withdrawn.

In arriving at the rejection, the Official Action also recites:

[a]s fiber is ingested and travels through the intestinal tract it, essentially, scrapes the niches, folds or walls of the intestinal tract thereby removing or replacing potentially toxic bacteria that reside on the surface of the intestinal walls. Because deposition of these potentially toxic pathogens on the intestinal walls tend to manifest as precursors for intestinal disorders and diseases, it is important to regularly rid the intestinal tract of the potential pathogen . . . One would have been motivated to modify the teachings of Green with the expectation that fiber hastens the amount of time it takes for feces to be eliminated, thereby minimizing the colon's exposure to naturally occurring carcinogens or pathogens - including byproducts of intestinal bacteria. (pages 4-5 of the Official Action).

First, it should be noted that the assertions made in the above line of reasoning are unsupported by any evidence of record. Accordingly, support for these assertions is respectfully requested. Second, even assuming *arguendo* that the above assertions are correct, the references of record would still fail to teach or reasonably suggest the claimed invention. In particular, there is an essential difference between systemic infections caused by bacteria (i.e., infections which are bloodborne and which are affecting the body generally) and local infections caused by bacteria (i.e., infections which are not bloodborne and affect only a restricted part of the body). This difference has been repeatedly made clear in the specification. See, for example, page 7, lines 4-12, page 8, lines 1-20, page 11, lines 4-7, page 12, lines 6-14, page 13, lines 5-7, page 15, lines 16-17 and page 16, lines 8-10. Green, et al. and the other references of record are silent about the effect of the intake of dietary fibers, either orally, rectally or through tube feeding, on the treatment or inhibition of *systemic* infections caused by bacteria. Since the Official Action has not addressed this deficiency, it is respectfully submitted that a *prima facie* case of obviousness has not been established. Accordingly, it is respectfully submitted that the present invention is patentable over Green, et al.

Additionally, Claim 20 has been amended to clarify that the invention is directed to administration of *fermentable* dietary fibers. It is respectfully submitted that fermentable dietary fibers do not act in a way to scrape the niches, folds and walls of the intestinal tract in the asserted manner. Rather, fermentable dietary fibers are metabolized in the gastro-intestinal tract (see page 4, lines 14-19 of the specification). Therefore, these fibers are either already completely dissolved in the aqueous medium of the intestinal tract or are fermented by the intestinal bacteria with formation of soluble metabolites such as short-chain fatty acids. The action of fermentable dietary fibers in the gastro-intestinal tract is thus clearly different from the effect described in the Official Action. Accordingly, it is respectfully submitted that Claim 20 is patentable over the references of record.

For at least the reasons set forth above, it is also respectfully submitted that Claims 16-19 and 22-24, which depend from Claim 20, are also patentable over the art of record. Accordingly, it is respectfully requested that the rejection of these claims also be reconsidered and withdrawn.

Additionally, Claims 18 and 19 can be further distinguished from Green, et al.. Claim 18 depends indirectly from Claim 20 and further recites that “. . . the fiber is chicory inulin with an average degree of polymerization (\overline{DP}) of at least 20.” Claim 19 also depends indirectly from Claim 20 and further recites that “. . . the fiber is chicory inulin with an average degree of polymerization (\overline{DP}) of at least 25.”

The Official Action acknowledges that Green, et al. “. . . does not expressly teach inulin with an average degree of polymerization” (see page 3 of the Official Action). The Official Action, however, further states that:

[i]t is the position of the examiner, however, that this parameter fails to impart a patentable characteristic. What is the criticality of utilizing inulin with this degree of polymerization? (see page 3 of the Official Action).

The Official Action, however, has failed to indicate where *in the prior art* the suggestion or motivation to modify the teachings of Green, et al. to arrive at the invention set forth in Claims 18 and 19 can be found. Rather, the Official Action merely concludes that such a modification would have been obvious without providing a suggestion *in the prior art* of the desirability of modifying the teachings of Green, et al. Accordingly, it is respectfully submitted that Claims 18 and 19 can be further distinguished from Green, et al. Reconsideration and withdrawal of the rejection of these claims is therefore respectfully requested.

The Official Action also states that “. . . [a]pplicant has not shown any unexpected results obtained by utilizing inulin products with the claimed average degree of polymerization” (see page 4 of the Official Action). It is respectfully submitted, however, that the Applicant is under no duty to provide a showing of unexpected results. Rather, evidence of unexpected results can be used by an applicant to rebut a *prima facie* case of obviousness. See MPEP §716.02(a). In fact, it is well established that “[t]he lack of objective evidence of nonobviousness does not weigh in favor of obviousness”. Miles Labs. Inc. v. Shandon Inc., 997 F.2d 870, 878, 27 USPQ2d 1123, 1129 (Fed. Cir. 1993). See MPEP §716.01(a). As set forth above, the Official Action has failed to establish a *prima facie* case of obviousness. Accordingly, it is respectfully submitted that a showing of unexpected results is not necessary to patentably distinguish the instant claims from Green, et al.

Further, there is in fact objective evidence of non-obviousness in the specification which further distinguishes the claimed invention from Green, et al. Namely, the results of Examples 1 and 2 (which are graphically represented in Figures 1 and 2) illustrate the effect of fiber DP on the mortality of mice infected with *Listeria monocytogenes* and *Salmonella typhimurium*, respectively. In particular, Examples 1 and 2 illustrate that mice fed a diet including inulin fiber (i.e., a fructose polymer) had a significantly lower mortality rate than mice fed a diet containing

an oligofructose. The oligofructose used in the Examples (i.e., RAFTILOSE® P95) has an average DP of about 3.5 to 4.5 whereas the inulin fiber used in the Examples (i.e., RAFTILINE® HP) has an average DP of about 25 (page 3, line 20 - page 4, line 13 of the specification). RAFTILOSE® P95 is made by the partial hydrolysis of inulin (see page 3 of “Orafti Group, Press Information 2002”, a copy of which is attached hereto). Therefore, RAFTILOSE® P95 and RAFTILINE® HP are both fructose polymers which differ from one another in their average degree of polymerization. Accordingly, it is clear from the results of Examples 1 and 2 that the average DP of the fiber has a pronounced effect on the inhibition and/or treatment of systemic infections.

According to MPEP § 716.01(a), objective evidence of non-obviousness *must be considered* whenever present. Further, “[e]xaminers must consider comparative data in the specification which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness of the claims”. In re Margolis, 785 F. 2d 1029, 228 USPQ 940 (Fed. Cir. 1986). It is respectfully submitted that the evidence of non-obviousness set forth in the specification, when properly considered, further distinguishes the claimed invention from Green, et al.

Claim 22 can also be further distinguished from Green, et al. Claim 22 depends from Claim 20 and further recites that “. . . the pathogenic bacteria is selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella*”. There is no teaching or suggestion in Green, et al. of a method of treating and/or inhibiting a systemic infection caused by pathogenic bacteria selected from the group consisting of *Clostridia*, *Bacteroides*, *Listeria*, *Candida* and *Salmonella* as set forth in Claim 22.

Claims 23 and 24 can also be further distinguished from Green, et al. Claim 23 depends indirectly from Claim 20 and further recites that “. . . the human or vertebrate is an adult human

and the amount of fiber administered to the adult human ranges from 5 to 40 g/day.” Claim 24 depends indirectly from Claim 20 and further recites that “. . . the human or vertebrate is an adult human and the amount of fiber administered to the adult human ranges from 5 to 25 g/day.” There is no teaching or suggestion in Green, et al. of a method of treating and/or inhibiting a systemic infection caused by pathogenic bacteria in an adult human comprising administering from 5 to 40 g/day or from 5 to 25 g/day of a fructan as set forth in Claims 23 and 24.

Newly Cited Prior Art

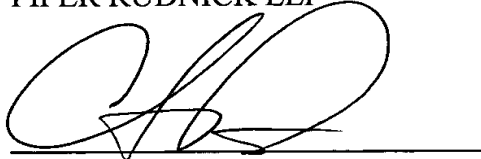
The references cited on the attached Information Disclosure Statement also fail to teach or reasonably suggest the claimed invention. In particular, none of the cited references teach or reasonably suggest methods as claimed comprising administering to humans or vertebrates having systemic infections (Claim 20) a composition containing an effective amount of a dietary fiber or a mixture of dietary fibers, wherein the composition is administered orally, through tube feeding or rectally. As such, it is respectfully submitted that the pending claims are also patentable over these references.

CONCLUSION

Since all of the pending claims are believed to be in condition for allowance, prompt issuance of a Notice of Allowability is respectfully requested. If there are any other questions, the Examiner is encouraged to call the undersigned attorney at the phone number listed below.

Respectfully submitted,

PIPER RUDNICK LLP

A handwritten signature in black ink, appearing to be 'S. Kelber', written over a horizontal line.

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MARKED-UP COPY OF AMENDED CLAIMS

20. (Twice Amended) A method for the inhibition and/or treatment of systemic infections in humans or vertebrates comprising administering to humans or vertebrates having a systemic infection caused by [pathogenic bacteria] a composition [containing] comprising an effective amount of a fermentable dietary fiber or a mixture of fermentable dietary fibers, wherein the composition is administered orally, through tube feeding or rectally.